

PSJ3

Exhibit 672

1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 -----) MDL No. 2804

5 IN RE: NATIONAL)

6 PRESCRIPTION OPIATE)

7 LITIGATION)

8 -----) No. 1:17-MD-2804

9 THIS DOCUMENT RELATES TO:)

10 ALL CASES)

11 -----) Hon. Dan A. Polster

12

13 HIGHLY CONFIDENTIAL

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15

16 The videotaped deposition of MICHAEL M.

17 MILLER, M.D., called by the Plaintiffs for

18 examination, taken pursuant to the Federal Rules of

19 Civil Procedure of the United States District Courts

20 pertaining to the taking of depositions, taken before

21 JULIANA F. ZAJICEK, a Registered Professional Reporter

22 and a Certified Shorthand Reporter, at the offices of

23 Foley & Lardner, Suite 400, 150 East Gilman Street,

24 Madison, Wisconsin, on June 4, 2019, at 10:00 a.m.

1 Q. Dr. Miller, we are back on the record
2 after a short break.

3 We were just discussing the last
4 pharmaceutical company that you worked for that's on
5 your CV, US WorldMeds.

6 Do you recall that?

7 A. Yes, ma'am.

8 Q. Okay. We had briefly started talking
9 about the first entry for US WorldMeds which was an
10 advisory group.

11 Is -- am I correct that in that advisory
12 group one of the things you were advising on was the
13 slide deck for later speakers bureaus for a drug for
14 US WorldMeds?

15 A. Yes.

16 MS. HIBBERT: Objection to form.

17 THE WITNESS: Oh, sorry.

18 BY MS. DICKINSON:

19 Q. Okay. And what was the drug?

20 MS. HIBBERT: Objection to form.

21 BY THE WITNESS:

22 A. The tradename is L-u-c-e-m-y-r-a.

23 BY MS. DICKINSON:

24 Q. And from your experience with

1 pharmaceutical company speakers bureaus, I think you
2 testified, but I just want to make sure, that the way
3 that the speakers bureau systems works is that
4 speakers are handed a slide deck drafted by the
5 pharmaceutical company, is that true?

6 A. That's the way I understand it to be.

7 Q. In your experience, are speakers that are
8 paid speakers in a speakers bureau for pharmaceutical
9 companies allowed to make revisions to that slide
10 deck?

11 MS. HIBBERT: Objection to form, calls for
12 speculation.

13 BY THE WITNESS:

14 A. Speakers are instructed that they should
15 not go off script, but if they want to put in their
16 own slides, they have to identify them as their own
17 slides and not the company's slides.

18 BY MS. DICKINSON:

19 Q. And the script, the original script comes
20 from whichever pharmaceutical company is sponsoring
21 the speakers, correct?

22 A. Yes.

23 MS. HIBBERT: Objection to form.

24 BY MS. DICKINSON:

1 Q. Okay.

2 MS. HIBBERT: Dr. Miller --

3 THE WITNESS: Sorry.

4 MS. HIBBERT: -- give me a pause, please.

5 THE WITNESS: Sorry.

6 BY MS. DICKINSON:

7 Q. Which pharmaceutical companies have you
8 served on the speakers bureau for, could you give me a
9 list of those?

10 A. BDSI and US WorldMeds.

11 Q. You mentioned Ammon Labs.

12 Did you serve on the speakers bureau for
13 Ammon Labs?

14 A. That's a different deal, but, in fact,
15 yes. They -- they don't really have it well formed,
16 but I've given talks on their behalf and been
17 compensated for them.

18 Q. Okay. You mentioned an additional company
19 that makes Vivitrol, I believe.

20 What is the name of that company?

21 A. A-l-k-e-r-m-e-s.

22 Q. Have you ever served on the speakers
23 bureau for Alkermes?

24 A. No.

1 presented an agenda to react to, and back then the
2 PTACs met either four to six times a year. I think
3 they met less and less during the time and they've
4 become less and less influential since 1998, but the
5 PTACs were a big deal back in the '90s.

6 Q. Your experience as the chair of the -- can
7 we call it the PTAC committee, is that fair?

8 A. The PTAC, yes.

9 Q. Okay. Was Joint Commission hospital
10 accreditation important to the hospitals?

11 A. Oh, yes.

12 Q. Why?

13 A. It has to do with stature and prestige.
14 You don't want to be unaccredited. So it's like a
15 Good Housekeeping seal or a Consumer Reports seal.
16 That's extremely important. But there was a bottom
17 line consideration as well, and that is something that
18 I will call "deemed status." And this was set up by
19 the Federal Government.

20 The Centers for Medicare and Medicaid
21 Services are the branch of the Federal Department of
22 Health & Human Services that oversees the Medicare and
23 Medicaid program and how they pay inpatient,
24 outpatient, nursing home, healthcare providers for

1 healthcare services, okay.

2 To be a hospital that receives Medicare
3 payments, you have to be surveyed by CMS. The CMS
4 gave deemed status to the Joint Commission years ago,
5 and by that they mean if you have been surveyed by the
6 Joint Commission, you are deemed to be surveyed by
7 CMS. And so the Joint Commission surveys serve in
8 lieu of a government survey to determine if you are
9 eligible to receive Medicare services. Therefore, if
10 you lose Joint Commission accreditation, you lose your
11 ability to get paid by Medicare and Medicaid. You
12 might imagine the impact that would have on a
13 hospital.

14 Q. It's a huge financial impact, correct?

15 MS. HIBBERT: Objection to form.

16 BY THE WITNESS:

17 A. Exactly, that's the point I was trying to
18 make.

19 BY MS. DICKINSON:

20 Q. You made -- you actually made it very
21 clear, in an area that is really complicated. I
22 appreciate it. I used to defend hospitals years ago
23 and I'm not sure I ever heard someone put it that
24 succinctly.

1 other courses with her ever at UW?

2 A. You know, I don't even know if it's in my
3 CV, but it might be. Over the years I have been asked
4 to present to classes in the law school, in the social
5 works school, in the pharmacy school, maybe even the
6 physical therapy school, maybe even the vet school,
7 I -- you know, but people just call up and say, We've
8 heard you are a good speaker or we need an expert.

9 And so I've probably taught in one of June's courses
10 where I'd come in for one session and teach a session.

11 Q. Okay. We talked about your work on the
12 PTAC for the Joint Commission back in 1998.

13 Did you ever come into contact with either
14 Dr. Dahl or Dr. Joranson during your time working on
15 that committee?

16 A. Yes.

17 Q. Okay. When?

18 A. My last year.

19 Q. Okay. And then is -- was that 1998?

20 A. I believe so.

21 Q. Okay. What was the substance of that
22 contact?

23 A. A presentation was made to the PTAC about
24 the idea of a new standard to put in -- in the manual.

1 Q. Okay. And when you say "the manual," we
2 are talking about this CAMH?

3 A. CAMH, yes, ma'am.

4 Q. Okay. And was -- that presentation was
5 made by Dr. Dahl and Dr. Joranson?

6 MS. HIBBERT: Object to form.

7 BY THE WITNESS:

8 A. No.

9 BY MS. DICKINSON:

10 Q. Okay. I'm sorry. Who made that
11 presentation?

12 A. Dr. Joran- -- Dr. Dahl and another person
13 whose name I don't recall.

14 Q. Was that other person someone at the UW
15 pain and policy group?

16 MS. HIBBERT: Objection to form.

17 BY THE WITNESS:

18 A. To the best of my recollection, it was
19 not.

20 BY MS. DICKINSON:

21 Q. Okay. Was that other person someone from
22 the University of Wisconsin?

23 A. To the best of my knowledge, it was not.

24 Q. Okay. Do you know what entity that other

1 person was affiliated with?

2 MS. HIBBERT: Objection to form.

3 BY THE WITNESS:

4 A. No.

5 BY MS. DICKINSON:

6 Q. Were there more than just Dr. Dahl and
7 this other person that you don't recall making that
8 presentation to the PTAC regarding the CM -- CAMH
9 standards?

10 A. Yes.

11 Q. Okay. Who else was making the
12 presentation?

13 A. The Joint Commission staff.

14 Q. Okay. Which Joint Commission staff?

15 A. I have no idea what their name was. I
16 don't remember if they worked for what was called
17 the -- the SSP, the Standards and Survey Processes
18 committee, which was one level up, if I can digress
19 for a second --

20 Q. Yes.

21 A. -- the Joint Commission has a Board of
22 Commissioners which is like the board of directors.
23 The SSP reports to them and oversees standards and
24 survey procedures across all of the accreditation

1 programs for the Joint Commission. And then each of
2 the accreditation programs, as I mentioned, ambulatory
3 care, behavioral care, hospitals, long-term care, each
4 of those had a PTAC.

5 So the SSP was in between the PTACs and
6 the -- and the Board of Commissioners. So to get a
7 new standard, staff has to conceptualize it, you have
8 to present it to the PTAC and the PTAC has to approve
9 it. It goes to the SSP, this is the way it was then,
10 the SSP has to review it and approve it. If they
11 approve it, it goes to the Board of Commissioners and
12 the Board of Commissioners has to approve it and it
13 gets put in the book. That was the process.

14 And I don't remember if it was formally
15 somebody that worked for SSP or if it was just a staff
16 member, pardon the phrase, in the bowels of the Joint
17 Commission, who came, but it was a proposal of a new
18 standard.

19 Q. Okay. And what was the content of the
20 proposal of the new standard that Dr. Dahl and the
21 others were --

22 MS. HIBBERT: Objection.

23 BY MS. DICKINSON:

24 Q. -- presenting on?

1 MS. HIBBERT: Sorry. Same objection.

2 BY MS. DICKINSON:

3 Q. Go ahead.

4 A. The proposal was that there be a standard
5 in the manual that would address how the accredited
6 organization addresses pain complaints.

7 Q. And what were they proposing the
8 accredited organization would do to address pain
9 complaints?

10 MS. HIBBERT: Objection to form.

11 BY THE WITNESS:

12 A. To shorten our dialogue, they were
13 proposing what became known as the Joint Commission
14 pain standard.

15 BY MS. DICKINSON:

16 Q. Okay. The Joint Commission pain standard,
17 what was the general substance of the content of that?

18 MS. HIBBERT: Objection to form.

19 BY THE WITNESS:

20 A. Again, I don't have any opinions about
21 this. I have facts because I was there at the time.

22 BY MS. DICKINSON:

23 Q. Okay.

24 A. The Joint Commission pain standard says

1 that an accredited organization will be able to
2 demonstrate to the surveyors that it assesses patients
3 regularly regarding the status of any pain that they
4 may have.

5 Q. Did that standard that they were advocating --
6 advocating for require that every patient who came
7 into the hospital be assessed for pain?

8 Is that a short way of saying it?

9 MS. HIBBERT: Objection to form.

10 BY THE WITNESS:

11 A. That's fair.

12 BY MS. DICKINSON:

13 Q. Okay. Is this -- was the standards
14 summarizing what has been often called as the pain is
15 the vi -- fifth vital sign concept?

16 MS. HIBBERT: Objection to form.

17 BY THE WITNESS:

18 A. I will answer your question by saying that
19 that is an extraordinarily commonplace and inaccurate
20 conflation of two different concepts.

21 BY MS. DICKINSON:

22 Q. Okay. I -- I want to stick with what the
23 actual standard they were advocating for was.

24 A. That's good.

1 Q. And so the standard, you said, I think,
2 and I just want to be clear, the standard that they --
3 Dahl and the others were advocating for was that each
4 patient that came into the hospital setting would be
5 assessed for pain.

6 Is that accurate?

7 A. Yes.

8 Q. Okay.

9 A. To be -- to be clear, the fifth vital sign
10 language was never used by the Joint at that time.
11 Other people at the same time were developing the
12 concept of fifth vital sign. That was not the Joint
13 Commission.

14 Q. Okay. Do you know who else was developing
15 that concept, the fifth vital sign?

16 MS. HIBBERT: Objection to form.

17 BY THE WITNESS:

18 A. It came from some people, some clinicians,
19 some whatevers, some in California, and some in the
20 VA, both -- both California through some bureaucratic
21 arm of the state government and maybe the health
22 department, whatever. Somebody in California adopted
23 that term and some -- and the VA hospital system
24 developed that term, but they were never Joint

1 Commission terms.

2 BY MS. DICKINSON:

3 Q. Okay. Is pain a vital sign?

4 A. No.

5 MS. HIBBERT: Objection to form.

6 BY MS. DICKINSON:

7 Q. Do you --

8 MS. HIBBERT: Please.

9 BY MS. DICKINSON:

10 Q. -- the standard that we talked about with
11 respect to Dr. -- that Dr. Dahl was advocating for,
12 okay, so the Joint -- Joint Commission pain standard
13 change that she was advocating for, did you agree with
14 the change that she and others were advocating for?

15 MS. HIBBERT: Objection to form.

16 Again, this is far afield from the expert
17 opinions that Dr. Miller has offered in this case.
18 Are you asking his personal opinion in this question,
19 because he is clearly not offering an expert opinion
20 about anything that you have been asking about pretty
21 much this entire deposition since we haven't talked
22 about his substantive opinions once.

23 MS. DICKINSON: I am entitled to ask him about
24 his background. This is his background.

1 MS. HIBBERT: This is not background.

2 BY MS. DICKINSON:

3 Q. Doctor, please answer the question.

4 MS. HIBBERT: This is a -- this is a opinion
5 about a -- this is a question about an opinion that he
6 has not offered in this case.

7 MS. DICKINSON:

8 Q. Doctor, please answer the question.

9 A. May I?

10 Q. Did you agree with the -- with the change
11 in the standard that Dr. Dahl and others were
12 proposing?

13 MS. HIBBERT: Objection for the same reasons I
14 just stated.

15 BY MS. DICKINSON:

16 Q. Go ahead, Doctor.

17 THE WITNESS: May I proceed with the objection
18 on -- on the table?

19 MS. HIBBERT: You can proceed if you can answer
20 the question.

21 BY THE WITNESS:

22 A. I can answer the question.

23 BY MS. DICKINSON:

24 Q. I thought so. Go ahead.

1 MS. HIBBERT: Same objection.

2 BY THE WITNESS:

3 A. The PTAC advised that the standard not be
4 adopted.

5 BY MS. DICKINSON:

6 Q. And did you agree with the PTAC committee
7 that the standard should not be adopted?

8 MS. HIBBERT: Objection to form.

9 BY MS. DICKINSON:

10 Q. Go ahead.

11 A. I did.

12 Q. When you were on the PTAC committee, did
13 the standard get adopted?

14 A. It did not.

15 Q. Okay. Do you know if after you left the
16 committee that standard was adopted?

17 A. It was.

18 Q. Okay. When?

19 A. The following year.

20 Q. Do you know if Dr. Dahl had renewed her
21 request to the committee the following year when it
22 was adopted?

23 MS. HIBBERT: Objection to form, calls for
24 speculation.

1 BY THE WITNESS:

2 A. It -- it does call for speculation. I --
3 I -- I believe that it was the exact same process
4 presented to a differently composed PTAC, possibly
5 with more forceful arguments, but I believe the
6 process of presenting it was staff with these
7 excise -- ex -- external people with them and it was
8 adopted.

9 BY MS. DICKINSON:

10 Q. Okay. And was one of the external people
11 to your understanding when the process happened the
12 next year Dr. Dahl?

13 MS. HIBBERT: Objection to form.

14 BY THE WITNESS:

15 A. You asked me only to my understanding, and
16 I would say to my understanding, but I could be wrong.

17 BY MS. DICKINSON:

18 Q. Is it -- to your understanding is the
19 answer yes?

20 MS. HIBBERT: Objection to form, asked and
21 answered. He told you what he knew. He said he
22 doesn't know is his understanding.

23 BY THE WITNESS:

24 A. Yeah, I -- I don't --

1 Q. And so the standard, you said, I think,
2 and I just want to be clear, the standard that they --
3 Dahl and the others were advocating for was that each
4 patient that came into the hospital setting would be
5 assessed for pain.

6 Is that accurate?

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22 department, whatever. Somebody in California adopted
23 that term and some -- and the VA hospital system
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1 Commission terms.

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